K131724

DEC 2 4 2013

510(k) SUMMARY
MaxFuse VBR System

Sponsor:

Manufacturer/ (Owner):	Pioneer Surgical Technology, Inc. (RTI Surgical, Inc.) 375 River Park Circle Marquette, MI 49855
Phone:	(906) 225-5602
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Official Contact:	Emily M. Downs Sarah McIntyre
Date prepared:	December 19, 2013

Device Name: **MaxFuse Vertebral Body Replacement (VBR) System**

Classification Name: Spinal Vertebral Body Replacement Device

Classification: 21 CFR 888.3060 - Product code MQP, Class II

Predicate Devices:
Pioneer Vertebral Spacer (K061151)
DePuy Spine Bengal Stackable Cage System (K073649)
NuVasive Mesh VBR (K032476)

Description: The **MaxFuse VBR System** is a radiolucent, multilevel corpectomy system with VBR devices in a variety of footprint options, height options, and lordotic angle options to accommodate a wide variety of patient anatomy. The MaxFuse VBR devices may be used with bone graft.

Intended Use: The **MaxFuse VBR System** is indicated for use in the thoracolumbar spine (i.e., T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The MaxFuse VBR System is also indicated for treating fractures of the thoracic and lumbar spine. The MaxFuse VBR System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

The **MaxFuse VBR System** is intended for use with supplemental internal fixation systems cleared for the conditions listed above. The supplemental internal fixation systems that may be used include the Quantum Spinal Fixation System, Streamline TL Spinal Fixation System, and Streamline MIS Spinal Fixation System.

Materials: The **MaxFuse VBR System** implants are composed of ASTM F 2026 Polyetheretherketone (PEEK) with ASTM F 560 tantalum or ASTM F 136 titanium alloy radiographic markers.

Performance Data: Substantial equivalence was established through side-by-side testing to legally marketed predicate devices, including:

- ASTM F 2077: Static and Dynamic Axial Compression Bending and Static Torsion
- ASTM F 2267: Static Subsidence
- Draft Z8423Z, Submitted to ASTM F04.25.02.02: Static Expulsion

Substantial Equivalence: The subject and predicate systems are overall similar in:

- Intended Use
- Basic design: Single-unit VBR with radiographic markers, toothed surface, bone graft containment
- Materials: PEEK, Titanium alloy, Tantalum
- Sizes: Footprints, heights, lordosis comparable to predicates
- Mechanical Performance: equivalent results

There are no significant differences between the subject **MaxFuse VBR System** and the predicate devices which would adversely affect the use of the product. This submission supports the position that the subject system is substantially equivalent to previously cleared predicate systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 24, 2013

Pioneer Surgical Technology, Incorporated
Ms. Sarah McIntyre
Regulatory Affairs Associate II
375 River Park Circle
Marquette, Michigan 49855

Re: K131724
Trade/Device Name: MaxFuse VBR System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: October 25, 2013
Received: October 29, 2013

Dear Ms. McIntyre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K131724

Device Name: MaxFuse VBR System

Indications:

The MaxFuse VBR System is indicated for use in the thoracolumbar spine (i.e., T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The MaxFuse VBR System is also indicated for treating fractures of the thoracic and lumbar spine. The MaxFuse VBR System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

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Prescription Use ___√___ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices